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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,972	06/15/2000	Ada Goerlach-Graw	BMID 9941 US	8671

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THE LAW OFFICE OF JILL L. WOODBURN, L.L.C.
JILL L. WOODBURN
128 SHORE DR.
OGDEN DUNES, IN 46368

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,972	Applicant(s) GOERLACH-GRAW ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment dated 14 February 2005 has been received. Claims 15-26 are pending.

Claim Rejections - 35 USC § 112, first paragraph

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 recites that the detection zone is the last zone of the element that allows liquid transport and that it is devoid of a binding reagent that would enable detection of the analyte. Such a zone is not supported by the specification as originally filed.

Nowhere in the specification is there a specific recitation that the detection zone is the last zone that allows liquid transport, nor is there a specific recitation that the detection zone is devoid of a binding reagent.

Applicant asserts that support for this limitation is found throughout the specification as well as figures 1-4; however, a review of the specification does not yield proper support. Page 24, Example 1, recites a capture zone made of a fleece composed of 100 % linters, strengthened with two percent by weight Etadurin and having an absorptive capacity of 386 mL/m² and a thickness of 0.41 mm; and further recites that the detection zone is made of the same composition, i.e. a fleece of 100 % linters, strengthened with two percent by weight Etadurin with a thickness of 0.35 mm and an absorptive capacity of 372 ml/m². Even though this description of the detection does not include additional assay reagents, it does not specifically recites that no assay reagents are present. Therefore, because the various zones of the element are made of the same material, and the materials are recited as providing liquid transport between the zones, if the capture zone requires a capture reagent immobilized therein to capture the labeled conjugate in order for detection of the label in this area, it is expected that the detection zone would also have such a requirement, otherwise any labels present would diffuse away from the detection zone, rendering detection moot? Again, no support is found for the recitation of a detection zone being the last zone that allows liquid transport. The specification does not have any specific recitation of this limitation. Furthermore, even if it is true that the detection zone is the last zone of the element that allows liquid transport, this zone is still a liquid transport zone and thus would transport liquid away from the detection zone. In other words, this zone does not concentrate or absorb all liquid and hold it there.

Applicant is required to cancel the new matter in order to obviate this rejection.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 15-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is confusing with respect to the recitation of a detection zone which is devoid of a binding reagent that would enable detection of the analyte. Nothing else has been recited as enabling the detection of analyte in this zone, therefore, it is unclear how the *detection* zone works.

Response to Arguments

5. Applicant's arguments filed 14 February 2005 have been fully considered but they are not persuasive.

Applicant argues that the specification and the figures provide adequate support for the claims because the figures make it clear that the detection zone is the last zone of matrix on a support that is described as "not permeable to liquid, does not adversely affect the liquid flow of the matrix material and is inert with regard to the reactions which occur in the analytical element."

These arguments have been fully considered but are not persuasive. It is noted that the specification does not contain literal support for the claim limitation of a

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detection zone that is the last zone of the element that allows liquid transport and that the detection zone is devoid of a binding reagent that would enable detection of the analyte.

First, it appears that Applicant is attempting to redefine the term “detection” and “detection zone” because a detection zone that is “devoid of a reagent that would *enable detection of the analyte*” is not properly a “detection zone”. It is understood that Applicant is attempting to claim a zone for detecting the result of an assay and that this zone does not contain specific binding reagents for the analyte or the labeled binding partners to the analyte, however, the wording of the claim is open to different interpretation. Therefore, where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. This feature of the claim is indefinite because the specification does not clearly define this feature. Applicant argues that by virtue of the absent of a discussion regarding any reagent in the detection zone, the specification adequately provides support for the limitation of a detection zone that is *devoid* of binding reagent that would enable detection of the analyte. However, the mere absence of a positive recitation is not a proper basis for exclusion. Any claim containing a negative limitation or exclusionary proviso must have basis in the original disclosure. Since the specification does not provide literal or implicit support with reasonable clarity, and

since this is a critical limitation of the claimed invention, the claimed element is considered to be new matter.

Second, Applicant argues that because the detection zone is the last zone on the support that allows liquid transport, if any analyte is present, the complex comprising the labeled reagents and the analyte would migrate to the detection zone enabling detection of the analyte. This argument is not persuasive because it is not clear from the figures, nor has it been specifically discussed in the specification that the detection zone is the last zone on the support that allows liquid transport. In addition, even if the detection zone is the last zone on the support, there is nothing that prevents the complex to, at least, migrate to the end of the detection zone and overflow onto the support in the case that the detection zone becomes saturated, thus, rendering detection inaccurate. Furthermore, the support is recited as "not permeable to liquid, does not adversely affect the liquid flow of the matrix material and is inert with regard to the reactions", this is not proper support for the argument that the support does not allow lateral flow. If enough liquid is present, it will flow across a surface that is not "permeable", therefore, the specification does not have proper support for this feature.

Applicant argues that the specification provides an example of liquid transport by capillary force with absorbent capillary active material or various absorbent capillary-active material, and argued that by definition, capillary transport will stop once the availability of capillary-active material has ended. This argument is not persuasive. As stated above, even if it is true that the detection zone is the last zone on

the support that is made of an absorbent material, it is the office's position that the device can still transport liquid. The specification, at page 5, starting at line 20, also teaches other types of liquid flow including capillary flow, mainly, the specification discloses that liquid flow is possible in a suitably prepared hollow body by means of gravitational force. Therefore, the non-liquid absorbent support can transport fluid flow by gravitational force as taught by the specification, rendering any detection in the detection zone moot.

Since all arguments have been addressed and since the claims are still deemed to lack proper support by the specification as originally filed, no claim is allowed.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
4/18/05